

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

ALBIHNS AS  
H. C. Andersens Boulevard 49  
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PCT

## NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

27.10.2004

Applicant's or agent's file reference  
P10417PC

### IMPORTANT NOTIFICATION

International application No.  
PCT/DK 03/00384

International filing date (day/month/year)  
11.06.2003

Priority date (day/month/year)  
11.06.2002

Applicant  
CHEMPAQ AS et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international  
preliminary examining authority:



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PATENT COOPERATION TREATY

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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P10417PC	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00384	International filing date (day/month/year) 11.06.2003	Priority date (day/month/year) 11.06.2002
International Patent Classification (IPC) or both national classification and IPC G01N15/00		
Applicant CHEMPAQ AS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  09.01.2004	Date of completion of this report  27.10.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Müller, T  Telephone No. +49 89 2399-2285 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/DK 03/00384**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

**Description, Pages**

1-15 as originally filed

**Claims, Numbers**

1-21 as originally filed

**Drawings, Sheets**

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	2,3,7,9,10,15-21
	No: Claims	1,4,5,6,8,11,12,13,14
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Reference is made to the following documents:**

- D1: US-A-4 835 457 (DELATOUR LEGAL REPRESENTATIVE ET AL) 30 May 1989 (1989-05-30)
- D2: US-A-4 521 729 (ROGGENKAMP HANS-GUNTHER ET AL) 4 June 1985 (1985-06-04)
- D3 EP-A-0 844 475
- D4: GB-A-2 232 769 (FISHER TIMOTHY CHARLES ; FISHER DR TIMOTHY CHARLES (US)) 19 December 1990 (1990-12-19)
- D5: US-B-6 230 8961 (LAMBERT DONALD L) 15 May 2001 (2001-05-15)
- D6: GR-B-1 002 424 (KAVVADIAS CHARILAOS) 30 August 1996 (1996-08-30)
- D7: WO 00/07254 A (NAT POWER PLC ; CLARK DUNCAN GUY (GB); MITCHELL THOMAS ANDERSON (GB) 10 February 2000 (2000-02-10)

The document D3 was not cited in the international search report. A copy of the document is appended hereto.

**2. Technical field:**

The application relates to a particle characterization apparatus in which particles, suspended in a conductive liquid pass through an orifice and are characterized utilizing determination of changes in the electrical impedance produced by comparatively non-conductive particles in an electrolyte.

**3. Problem:**

Disposable cartridges for blood sampling and handling including a membrane with an orifice for impedance cell sizing comprising a cheap, single-use membrane with a precision-machined orifice are required for blood cell analysis.

**4. Novelty (Article 33(2) PCT):**

The subject-matter of claims 1 and 4 is not new over D1 as required by Article 33(2) PCT.

Prior art document D1 discloses the technical features of claims 1 and 4, that is an apparatus for characterizing cells suspended in a liquid with a mixing chamber and

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a collection chamber (2a, 2b), separated by a membrane (5) containing an orifice for passage of the particles whose diameter is between 3  $\mu\text{m}$  and 5  $\mu\text{m}$ , said membrane made of plastic material (see D1, figure 1, column 2, lines 25-48 and column 4, line 13-column 5, line 30).

A similar argument would apply with respect to claims 8 and 11 (Article 33(2) PCT), see also section VIII of present preliminary examination report.

5. Furthermore, document D2 discloses problem and solution of disposable cartridges, that is a throw-away sample vessel with a plastic foil and a pore with a tolerance of 5%. Consequently the subject-matter of claims 1, 5, 6, 8, and 12 is not new over D2, see column 9, line 38-68 (Article 33(2) PCT).
6. Moreover, D3 discloses a particle sizing apparatus comprising a laser etched orifice in a polystyrene or PET flow restrictor (column 7, line 37-55). As consequence, the subject-matter of claims 13 and 14 is not new over D3.
7. Inventive step (Article 33(3) PCT):  
D3 discloses a tapered orifice (figure 8) for particle size determination. The employment of rounded edges, as claimed in claims 2, 3, 9, and 10 seems to be a design option which a skilled person would employ according to the circumstances without inventive step. Therefore the subject-matter of claims 2,3,9 and 10 does not meet the requirements of Article 33(3) PCT.
8. Claim 7 is not inventive because the subject-matter of claim 7 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to control the fluid flow.
9. Claims 15-21 are directed to standard details of laser machining, see for example D6 and D7, with no technical interrelationship to blood analysis or cell sizing. Therefore the subject-matter of claims 15-21 is considered to be not inventive as required by Article 33(3) PCT.

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**Re Item VIII**

**Certain observations on the international application**

1. Although claims 1 and 8 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT. A similar argument would apply to dependent claims 2-5 and 9-12 respectively.
2. The subject-matter of claim 5 is not clear (Article 6 PCT), because it seems to be contradictory to the subject-matter of claims 2 and 3, in that the diameter is either constant (claim 5) or has rounded edges (claims 2 and 3).